

FEB 03 2006

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0018

CUSTOMER NUMBER: 303

FORM APPROVED  
OMB NO. 0578-0038

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

AMENDED - 1/30/06

Wyeth Research Div Of Wyeth Pharm Inc  
500 Arcola Road - D5225  
Collegeville, PA 19426

Telephone: (215)-971-2810

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered by The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals in for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (C + D + E)
4. Dogs	57	541	230	59	830
5. Cats					
6. Guinea Pigs	624	898		186	1,084
7. Hamsters		529	101		630
8. Rabbits	118	958	288	55	1,301
9. Non-human Primates	69	804	55	30	889
10. Sheep					
11. Pigs		4			4
12. Other Farm Animals					
13. Other Animals					
Ferrets		630	39		669

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE

(b)(6), (b)(7)(c)

DATE SIGNED

1/24/06

*[Handwritten Signature]*

Attachment to APHIS Form 7023  
Column E Explanation for USDA Reporting Year  
October 1, 2004 through September 30, 2005

Registration Number: 23-R-0018

(b)(2)High, (b)(7)f

Fifty-nine dogs were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of gastrointestinal intolerance (emesis and or diarrhea) or one or more signs of organ system involvement (weight or body condition, cardiovascular signs, CNS signs, or anaphylaxis) were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by International drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

Thirty nonhuman primates were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of gastrointestinal intolerance, cardiovascular signs, and CNS signs were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by International drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

Fifty-five rabbits were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of gastrointestinal intolerance (diarrhea) or one or more signs of organ system involvement (Inappetence, ataxia, respiratory changes) were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff and any animals with severe or chronic signs of pain or distress were

provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by international drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

(b)(2)High, (b)(7)f

One hundred eight-six (186) guinea pigs were used in vaccine research as a disease model for genital herpes infection. Animals are infected and monitored. Animals develop lesions due to herpes virus. The study is designed to evaluate the efficacy of vaccine candidates that employ various alternative strategies in the treatment and prevention of human genital herpes infection. Use of anesthetics, analgesics or tranquilizers would interfere with assessment of the vaccine efficacy. Prior to conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results.

Attachment to APHIS Form 7023  
IACUC-Approved Exceptions for USDA Reporting Year  
October 1, 2004 through September 30, 2005

**Registration Number: 23-R-0018**

(b)(2)High, (b)(7)f

There was one IACUC-approved exception to the regulations and standards. Primates in a 13-week study were single-housed due to mature animal incompatibility issues.

(b)(2)High, (b)(7)f

There is one IACUC-approved protocol that requires an exemption to the Animal Care Standard stipulating provision of the opportunity to exercise for dogs. In this protocol, dogs are dosed with test compounds that have been labeled with radioisotopes. The dogs are housed in metabolism cages for the collection and quantification of feces and urine. The metabolism cages meet or exceed the minimum housing requirements for dogs as defined in the Animal Welfare Act, but do not provide sufficient space to exempt dogs from the plan for the opportunity to exercise.

Dogs are exempted from the Canine Exercise Plan for the duration of the radioisotope study. The requirement for the exemption is outlined in the IACUC-approved animal protocol, and a BioResources veterinarian documents each occurrence in the individual clinical record. Nine dogs were affected by this exemption in the past 12 months.

(b)(2)High, (b)(7)f

Two (2) dogs were excepted from exercise under an approved IACUC protocol. Radioisotopes were administered to the animals requiring the animals to remain in their cages in order to collect urine, blood and stool samples. During this time (7 days or less), the dogs were not allowed out of their cages to exercise. After completion of the study (7 days or less), the dogs were allowed to exercise daily in a confined area in order to contain any residual radioactivity they may excrete while outside their cages. Once it was determined that the amount of radioactivity in the dogs' urine and feces fell below approval limits, the dogs were returned to the general pool.